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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,574	10/28/2003	Denis Barritault	1003-DIV-01	4857

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IP GROUP OF DLA PIPER US LLP
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 4900
PHILADELPHIA, PA 19103

EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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06/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/695,574

Applicant(s)

BARRITAU LT ET AL.

Examiner

Susan E. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42 and 61-66 is/are pending in the application.
- 4a) Of the above claim(s) 42 and 61-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65 and 66 is/are rejected.
- 7) ☒ Claim(s) 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20, 2006, including the 132 declaration, has been entered.

Claims 1-41 and 43-60 are cancelled. Claims 42 and 61-66 are pending.

Election/Restrictions

Applicant's election with traverse of Group II, claims 65 and 66, in the reply filed on November 20, 2006, is acknowledged. The traversal is on the ground(s) that there is lack of any evidence of burden since the groups of claims are classified in the same sub-class, and therefore, can be readily examined together. This is not found persuasive because burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further still, the polymers of Groups I and II are distinct (presence of Z in Group II), thus requiring separate searches. Therefore, searching the instant two patentably distinct inventions would, in fact, impose a serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 42 and 61-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 65 and 66 are examined on the merits to the extent they read on the elected subject matter.

Claim Objections

Claim 65 is objected to because of the following informalities: At line 7, the claim recites that X is “-COO-Na⁺,” which should be replaced with “-COO⁻Na⁺”. At line 8, the claim recites that Y is “-CO-CH₂-CHOH-CH₂-SO₃-Na⁺” which should be replaced with “-CO-CH₂-CHOH-CH₂-SO₃⁻Na⁺”. At line 14, the claim recites that X is “-CH₂-COO-Na⁺” which should be replaced with “-CH₂-COO⁻Na⁺”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *in vitro* use of RGTA 1112 and 1113 (CM₂DPheS2 and CM₃DTyrS2, shown in Figure 26) for treating **factors involved in fibroses**, does not reasonably provide enablement for treating fibroses with all other AXYZ polymers. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Regarding undue experimentation, *In re Wands*, 8 USPQ2d 1400, at 1404 (Fed. Cir. 1988) states:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (Citations omitted).

The rejected claims are drawn to the method of treating fibroses (including fibroses of smooth muscle and mesenchymal tissues) by administering a pharmaceutical composition comprising the XYZ polymer. The claims are broad enough to encompass an infinite number of polymers, of which experimentation would be required for every single variant to determine their efficacy as antifibrotic agents. For the treatment of fibroses, Z is further limited to phenylalanine and tyrosine, as is shown in Figure 26 (CM₂DPheS₂ and CM₃DTyrS₂).

Though the specification demonstrates through *in vitro* experiments that the XYZ polymers CM₂DPheS₂ and CM₃DTyrS₂ are suitable for the treatment of fibroses, no experiments are described for the testing of all other XYZ polymers for their efficacy in treating fibroses. The specification does not provide actual guidance or evidence supporting the use of each and every polymer defined by claims 65 and 66 in treating fibroses.

In sum, a skilled artisan would have expected to have had to engage in an essentially trial and error process, with little guidance from the specification as filed, to determine suitable

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XYZ polymers which treat every type of fibrosis. Such a trial and error process clearly constitutes undue experimentation.

Claims 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

First, claim 65 comprises new matter. The recitation of what Z represents at lines 9-12 of claim 65 is considered new matter. Page 22, lines 1-5 indicates that when A is $-(O-CH_2-CH_2-CO)-$, X is $-COOH$ or $-COO^-Na^+$, and Y is $-CO-CH_2-CHOH-CH_2-SO_3H$ or $-CO-CH_2-CHOH-CH_2-SO_3^-Na^+$, then Z is $-CO-OCH_3-CH(CH_2-CH_3)-CH_3$. The specification does not specify in any other instance that in the case where A, X, and Y are defined as above, that the Z is any other compound. Additionally, the recitation that "Y is $=SO_3H$ or $SO_3^-Na^+$ " (emphasis added) in claim 65 is new matter since the disclosure teaches that in the case where A is a glucose monomer, X is $-CH_2COOH$ or $-CH_2COO^-Na^+$, Y is " $-SO_3H$ or $SO_3^-Na^+$ " (emphasis added). See page 29. Clearly the specification as filed requires that there is a single bond from SO_3H .

Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

Response to Arguments

Applicant's arguments filed November 20, 2006, and July 3, 2006, have been fully considered but they are not persuasive with respect to claims 65 and 66. Regarding *in vitro* tests for supporting the assertion of therapeutic utility of the claimed AXYZ polymers, applicant's arguments filed on July 3, 2006, the Papy-Garcia declaration filed on July 3, 2006, and MPEP 2107.03, have been considered. The treatment of fibroses is enabled for the AXYZ polymers listed in Figure 26 (specifically, CM₂DPheS2 and CM₃DTyrS2) given the data from *in vitro* experiments shown on Figure 26. However, no *in vitro* testing and results had been provided for demonstrating the efficacy of all other AXYZ polymers encompassed by the claims under examination. Thus, the enablement rejection must be maintained for the treatment of fibroses by AXYZ polymers defined by claims 65 and 66 other than CM₂DPheS2 and CM₃DTyrS2.

No claims are allowed.

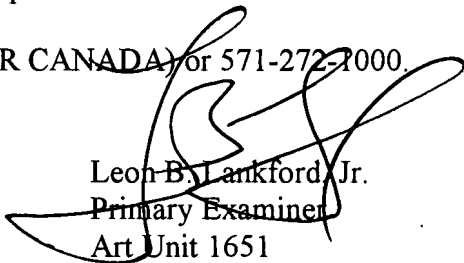
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan E. Fernandez
Assistant Examiner
Art Unit 1651



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651

sef